

ORTHOPAEDIC and REHABILITATION DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Panel met three times during the reporting period in Gaithersburg, Maryland.

The dates of the meetings were December 11, 2003, June 2-3, 2004, and August 31, 2004

The meeting on December 11, 2003, included a closed session to permit a discussion of trade secret or confidential commercial information.

ACCOMPLISHMENTS

At the December 11, 2003 meeting:

The Panel considered an FDA-initiated reclassification of the intervertebral body fusion cage device from class III to class II. The device is intended for spinal fusion procedures in skeletally mature adults with degenerative disc disease (DDD) at one or two levels from C2-C7 and L2-S1 using autogenous bone graft. The device does not include combination products, such as the intervertebral body fusion device using morphogenic proteins and scaffolds. The Panel recommended that FDA reclassify the device into class II using three special controls to reasonably assure the safety and effectiveness of the device: (1) a guidance document that may include clinical data for designs and materials beyond those currently approved; (2) device tracking for all implants not just cages for a limited period of time; and (3) testing guidelines, which include fracture toughness, potential response to wear particulates, and device retrieval analysis for a limited number of explanted devices.

Agency Action: FDA is drafting a reclassification rulemaking for this device.

Closed Committee Deliberations: On December 11, 2003, the meeting was closed to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future device issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

At the June 2-3, 2004 meeting:

On June 2, 2004, the open session, the Panel recommended conditional approval for Depuy Spine, Inc.'s PMA for Charité Artificial Disc. The device is intended for spinal arthroplasty in skeletally mature patients with degenerative disc disease at one level from L4-S1. The conditions were:

- A post-market study of all patients enrolled in the investigational device exemption (IDE) (including continued access patients) should be followed until the last-enrolled continued access subject reaches the 2 year time point, and the data will be provided the FDA.

Orthopaedic and Rehabilitation Devices Panel (continued)

- All patients treated with the device should be provided with documentation describing the specific components of their implant, including associated lot numbers, as well as a telephone number to be used for the reporting of any adverse events.
- A post-market *in-vitro* study to further assess wear debris.
- FDA should consider required surgeon training.
- FDA and the sponsor should discuss certain additional conditions and reach a mutually agreeable course of action. This discussion will consider whether these conditions should be addressed pre- or post-market.

On June 3, 2004, the Panel made recommendations to FDA regarding the Orthopedic Surgical Manufacturers Association's petition to reclassify the total mobile bearing knee (MBK) and unicompartmental MBK intended to replace the total knee or part of the knee joint, respectively, from class III into class II. The Panel recommended that FDA reclassify the total MBKs into class II. They suggested five special controls to reasonably assure the safety and effectiveness of the devices: (1) a special controls guidance document; (2) testing guidelines; (3) potential use of clinical data; (4) device specific training and labeling (to be negotiated with sponsors); and (5) patient identification cards (to include patient, surgeon, hospital, and implant information). They also recommended that FDA reclassify the unicompartmental MBK into class II. The Panel recommended the same special controls as identified for the total MBK, with a stronger emphasis placed on the use of clinical data. In addition, the Panel also urged post-market surveillance to track such adverse events as osteolysis, bearing dislocations, polyethylene failures, and revisions.

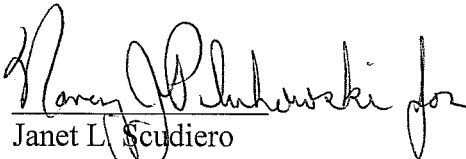
Additionally, the Panel made recommendations to the FDA regarding Orthopedic Surgeon Manufacturers Association's (OSMA) guidance document submission entitled Clinical Trial Design for Hip Replacement Systems. The main focus of the submission was a proposed clinical study design for evaluating the safety and effectiveness of total hip joint replacement systems. The design includes a composite endpoint consisting of three objective performance criteria as a control for patient success with a benchmark for overall study success and a 4% delta for noninferiority.

At the August 31, 2004 meeting:

In the open session, the Panel deliberated on St. Francis Medical Technologies, Inc.'s PMA for the X Stop Interspinous Process Distraction System. The device is indicated for patients aged 50 years or older suffering from neurogenic intermittent claudication secondary to mild or moderate lumbar spinal stenosis, who have undergone a regimen of nonoperative treatment and experience relief in flexion from their symptoms of leg/buttock/groin pain, with and without back pain. After deliberations, the Panel recommended that the PMA be found not approvable. The Panel cited several concerns regarding the data; they discussed several options for the sponsor to put the PMA in an approvable form.

September 30, 2004

Date


Janet L. Scudiero
Executive Secretary

Orthopaedic and Rehabilitation Devices Panel Roster

Chairperson

Michael J. Yaszemski, M.D., Ph.D.

Expertise: Orthopedic Surgery
Term: 11/13/02 - 8/31/05
Senior Associate Consultant and Associate Professor
Dept. of Orthopedic Surgery
Mayo Clinic and Graduate School of Medicine
200 1st Street SW
Rochester, MN 55905

Maureen A. Finnegan, M.D.

Expertise: Orthopedic Surgery
Term: 10/11/00 - 8/31/04
Associate Professor
Dept. of Orthopaedic Surgery
Univ. of Texas Southwestern Medical Center
5323 Harry Hines Blvd.
Dallas, TX 75390-8883

Richard J. Friedman, M.D.

Expertise: Orthopedic Surgery
Term: 11/13/02 - 8/31/06
Clinical Professor of Orthopaedic Surgery
Medical University of South Carolina
2270 Ashley Crossing Dr. Suite 110
Charleston, SC 29414

Choll W. Kim, M.D., Ph.D.

Expertise: Spinal Surgery; Biomaterials
Term: 9/1/04 - 8/31/08
Assistant Professor--Spine Surgery
Dept. of Orthopaedic Surgery
Univ. of California, San Diego
3350 La Jolla Village Dr., MC#112D
San Diego, CA 92161

John S. Kirkpatrick, M.D.

Expertise: Orthopedic Implants
Term: 11/13/02 - 8/31/06
Associate Professor
Dept. of Surgery, Div. of Orthopaedic Surgery
Univ. of Alabama School of Medicine Faculty
510 20th St South FOT-Suite 940
Birmingham, AL 35294-3295

Executive Secretary

Janet Scudiero

Center for Devices and Radiological Health
Office of Device Evaluation/DGRND
9200 Corporate Blvd. HFZ-410
Rockville, MD 20850
(301) 594-1184 X 176
(301) 594-2358

Kinley Larntz, Ph.D.

Expertise: Biostatistics
Term: 11/13/02 - 8/31/05
Professor Emeritus
Dept. of Applied Statistics
University of Minnesota
6339 East Greenway, #102-172
Scottsdale, AZ 85254-6517

Stephen Li, Ph.D.

Expertise: Biomaterials; Materials Science
Term: 10/11/00 - 8/31/04
President
Medical Device Testing and Innovations
1469 Tallevast Road
Sarasota, FL 34243

Sanjiv H. Naidu, M.D., Ph.D.

Expertise: Orthopedic Surgery
Term: 11/13/02 - 8/31/06
Associate Professor of Orthopaedic Surgery
Dept. of Orthopaedics and Rehabilitation
Pennsylvania State Univ., Hershey Medical Ctr
500 University Dr.
Hershey, PA 17033

Sally A. Rudicel, M.D.

Expertise: Orthopedics Surgery
Term: 9/1/04 - 8/31/08
Associate Professor
Dept. of Orthopaedics
Tufts Univ., New England Medical Center
750 Washington Street
Box 306
Boston, MA 02111

****Sally Maher, ESQ**

Expertise: Bacteriology
Term: 12/31/00 - 8/31/04
Senior Director, Regulatory Affairs
Clinical Research
Smith & Nephew Endoscopy
150 Minuteman Road
Andover, MA 01810

** Industry Representative